





Presented by Management Forum

# Medical Device Regulation in the Eurasian Union, Russia and the CIS

**23-24 July 2025** + 9-10 December 2025

A comprehensive overview of medical device regulatory affairs in Russia and the Eurasian Union. Key countries covered include Armenia, Azerbaijan, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan and Ukraine. දු\_\_ Format:

Live online

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**CPD:** 12 hours for your records ്വീ

Certificate of completion

# **About this Programme**

The aim of this event is to provide a comprehensive overview of medical device regulatory affairs in Russia and the Eurasian Union. This interactive course will cover the regulatory requirements within these regions, focusing on practical aspects to assist in developing your regulatory strategy for product approval. The presentations will also give practical hints on the regulatory and registration process where possible.

#### Benefits of Attending Attending

#### this programme will:

- Give you the full background to the CIS medical device market
- Ensure that you understand the full implications of the new regulations which will affect how you do business in the Eurasian Economic Union (EAEU)
- Help clarify the document requirements and timelines of national procedures and EAEU registration procedures
- Fully update you on the national regulations in Russia, Belarus, Kazakhstan, Ukraine and other CIS countries

#### Who Should Attend? This seminar

#### will be of particular interest to:

- Personnel working in medical device regulatory affairs in this region
- Anyone who is considering marketing a medical device in this region
- Those interested in an update on recent developments

# Programme

#### Day 1

#### Russia and CIS - Regional Regulatory Overview

- Russia and CIS Market Overview
- Market protection policies
- CIS in regional and international
- Regulatory
- Harmonisation

#### Eurasian Regulations for Medical Devices

- Countries current members of EAEU and EAEU Official bodies
- Terms of transition period
- EAEU Registration Procedures
- Application process
- EAEU submission documents and data requirements
- QMS inspections

#### **Registration of MDs in Russia**

- Regulatory authorities in Russia
- Key regulations governing registration process
- Clinical trials for medical devices
- National registration procedures

### Day 2

#### Registration of MDs in Russia (continued)

- Application dossier and data requirements
- Post approval life cycle maintenance applications
- Safety reporting and market surveillance
- Price and reimbursement
- Patent data protection

#### Common regional requirements in CIS

 Administrative data, translations, normative document, samples, labelling

#### **Registration of MDs in other CIS countries**

- Other EAEU members: Kazakhstan, Belarus, Armenia, Kirgizstan
- EU harmonisation: Ukraine, Moldova, Georgia,
- National procedures: Azerbaijan, Uzbekistan, Tajikistan, Turkmenistan

#### Workshop – CIS Regional Regulatory Strategy



## Presenter



#### Anna Harrington-Morozova

Anna Harrington-Morozova is a regulatory, drug development and external relations professional with over 20 years' experience gained working in a Regulatory Authority, academia and industry. Anna graduated in Russia as a pharmacist. After working in the Russian Ministry of Health and the Clinical Pharmacology Department of Moscow Medical University, she held regulatory and external relation positions in the pharmaceutical industry and CROs in Russia and the UK, including senior regulatory affairs posts in GSK,EISAI, ICON and PRA. Anna currently acts a a Scientific and Reguatory director at Regem Consulting Ltd – a consultancy which focuses on drug development, global regulatory advice, professional trainings and flexible resourcing solutions for the pharmaceutical, biotech and medical device industries in emerging markets.



# **Course dates**

23-24 July 2025	<b>Live online</b> 09:00-17:00 <b>UK (London)</b> (UTC+01) <i>Course code 14791</i>	GBP <b>1,299</b> <del>1,499</del> EUR <b>1,819</b> <del>2,099</del> USD <b>2,087</b> <del>2,399</del> Until 18 Jun
9-10 December 2025	<b>Live online</b> 09:00-17:00 <b>UK (London)</b> (UTC+00) <i>Course code 15134</i>	GBP <b>1,299</b> <del>1,499</del> EUR <b>1,819</b> <del>2,099</del> USD <b>2,087</b> <del>2,399</del> Until 04 Nov

### How to book

**Online:** 

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ipi.academy/2289

Alternatively contact us to book, or if you have any queries:

Email:

info@ipiacademy.com

**Phone:** +44 (0)20 7749 4749

### Discounts

- Booking more than one delegate on any one date qualifies for a **15% discount** on the second and subsequent places.
- Most events qualify for an early booking discount prior to 6 weeks before the course date. Be sure to check on our website, where the latest discounts will be shown.

### **Further information**

#### Fee

The fee includes all meals and refreshments for the duration of the course (for venue-based courses) and a complete set of course materials (provided electronically). If you have any particular requirements, please advise customer services when booking.

#### Please note

IPI Academy (and our training partners) reserve the right to change the content and timing of the programme, the speakers, the date and venue due to reasons beyond their control. In the unlikely event that the course is cancelled, we will refund the registration fee and disclaim any further liability.

#### Terms and conditions

The rest of the our terms, the event cancellation policy and the terms and conditions are on our website, please visit jpi.academy/content/terms-and-conditions



## **Reviews**

#### \*\*\*\*

Overall the course is well organized, contains relevant information and provides a good starting point for registration activities in the covered geographical area. I think if a person gets responsibility for regulation in EUEA, Russia, Ukraine, Kazakhstan and Belarus countries – this course is a great source of relevant information.



**Elena Dolgodilina** Regulatory Affairs Manager Geistlich Apr 3 2025

#### \*\*\*\*

The speaker was excellent and shared a lot of interesting information regarding national registration in the CIS region. All in all, it was good and useful webinar.



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I liked how structured it was and that it was practical and we could ask specific questions. The exercises at the end were interesting as well.



#### **★★★★**☆

Speaker was really good and easy to understand for a non-native english speaker as I am. Organization of webinar was perfect. The assistance attendent was here for us in case of any problems. Content was complete and detailed as awaited. Good speaker and very friendly.



# Run this programme in-house for your whole team

Coming to IPI Academy for your in-house training provides an all-inclusive service which gives you access to a wide variety of content, learning platforms and delivery mechanisms as well as your own personal training adviser who will work with you from the initial enquiry through to feedback and follow-up after the programme.

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IPI Academy is a training initiative of Falconbury and Management Forum; leading providers of industry training for over 30 years, based in the UK.

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